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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/576,052 | 11/01/2006 | Paul William Glue | 33427-US-PCT | 6943 |

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

12/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/576,052

Applicant(s)

GLUE ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicants' Amendment filed September 19, 2008 is acknowledged. Claims 1-8 remain under consideration.

A Declaration of Eckhard Weber under 37 CFR § 1.132 filed September 19, 2008 is further acknowledged and has been considered.

The objection to the disclosure that was set forth in the last Office Action is withdrawn subsequent to an amendment to claim one.

Claims 1-8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Doi et al., US 2004/0058914, in the last Office Action. It was asserted Doi teaches the administration of the neurokinin receptor antagonist DNK 333, which is N-[(1R,2E)-1-[(3,4-dichlorophenyl)methyl]-4-[[[(3R)-hexahydro-2-oxo-1H-azepin-3-yl]amino]-4-oxo-2-buten-1-yl]-N-methyl-3,5-bis(trifluoromethyl)-benzamide, the compound of instant claim 7, in the treatment of urinary incontinence. See claims 1, 5 and 6, pages 29-30. The claims differ in that Doi requires combination therapy with an anti-cholinergic agent represented by formula I.

Applicants argue the Doi reference does not provide any experimental evidence that the disclosed compounds are effective in treating urinary incontinence. Applicants refer to Experimental Examples 1 and 2 and urge the model used would generate results with respect to the treatment of an inflammatory condition and would not indicate whether or not the compounds effective in treating cystitis would be effective in treating urinary incontinence.

Doi's teaching clearly encompasses methods of treating urinary incontinence as evidenced by the multiple recitations thereto throughout the disclosure, as well as in the

claims and Experimental Examples. See page 29, paragraph [0506]. A review of Experimental Example 1 shows one particular animal model in which combined administration of compounds - that does not include DNK 333 - results in increased bladder capacity following cyclophosphamide-induced pollakiuria, an abnormal increase in the frequency of urination.

However, because Doi states superior treatment of the effects of urinary incontinence is achieved, following administration of neurokinin receptor antagonists, one skilled in the renal art would have been motivated to administer any among those recited compounds with a reasonable expectation of success. Motivation is provided to administer DNK 333 because the compound is a neurokinin receptor antagonist. A reference may be applied for all that it teaches.

An amendment to claim 1 replacing "comprises" with – consisting of – would obviate the rejection.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 27, 2008

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614